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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,471	11/04/1998	STEFAN ROSE-JOHN	012627-009	2240

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EXAMINER
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O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/20/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/142,471

Applicant(s)

ROSE-JOHN, STEFAN

Examiner

Eileen O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,7-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-5,7-9,11 and 12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1646

### **DETAILED ACTION**

1. Claims 1-5, 7-9, 11 and 12 are pending in the instant application. Claims 1, 7 and 11 have been amended as requested by Applicant in Paper Number 33, filed July 24, 2003.

Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-4, 7-9, 11 and 12 are currently under examination.

### ***Claim Objections***

2. Claim 4 is objected to because of the following informalities: the claim was copied incorrectly from the original claim. "I-6" should be "IL-6".

Appropriate correction is required.

### ***Withdrawn Objections and Rejections***

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1646

Claim 2 is indefinite because it recites the limitation "said ligand", and there is no antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 and 7-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sui et al, PNAS, Vol. 92, March 1995, and further in view of Wong et al, WO 96/04314, Feb. 15, 1996, for reasons of record in the previous Office Actions, Paper No. 17 at pages 6-7, Paper No. 23 at pages 5-7, Paper No. 26, and Paper No. 31, at pages 5-6, and below.

Applicant traverses the rejection and assert that the cited references, in combination or alone, fail to provide suggestion or motivation to modify the reference or combine reference teachings, fail to provide a reasonable expectation of success, and fail to disclose or suggest all of the claim limitations. Specifically, Applicant submits that Sui et al. do not disclose administering a IL-6/sIL-6R complex to cells, and that IL-6 and sIL-6R each alone, as well as the combination of IL-6 and sIL-6R, do not have any effect, and that only the combination of IL-6, sIL-6R and SCF is effective, and that Sui et al. only disclose using the combination of IL-6, sIL-6R and SCF and not the conjugate of the present invention, a fusion protein of IL-6 and sIL-6R without SCF. Applicant further asserts that the Wong et al. reference is irrelevant for a person skilled in the art looking to provide a product by which unbalanced interactions between proteins can be remedied, particularly in the case of an incomplete interleukin-6 receptor.

Art Unit: 1646

Applicant's arguments have been fully considered but are not deemed persuasive. Sui et al. does teach the administration of the IL-6/IL-6R **complex** (for example, see the sentence bridging the first and second columns on page 2860, and Table 1), but teaches that the administration of this complex alone, or SCF alone, had little effect in increasing expansion of hemopoietic progenitor cells, while the combination of IL-6/IL-6R complex and SCF was more effective. Wong et al. is relevant, since the reference teaches that it is advantageous to make fusion proteins (for example, reducing the complex to a single molecule to avoid separate purifications, enhanced yields and stability, and effective positioning of the components of the fusion protein). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to make a fusion protein, as taught by Wong et al., comprising IL-6 and IL-6R, since administration of a IL-6/IL-6R complex along with SCF increases expansion of progenitor cells, as taught by Sui et al., and a fusion protein comprising IL-6 and IL-6R would have advantages over administration of the separate proteins, as taught by Wong et al. Therefore, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

### ***Conclusion***

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1646

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

LORRAINE SPECTOR  
PRIMARY EXAMINER